

**REMARKS**

Upon entry of this amendment, claim 1 will be amended and claims 3, 22 and 23 will be canceled without prejudice or disclaimer of the subject matter recited therein so that claims 1 and 4-21 and 24-29 will remain pending.

By the amendment herein, claim 1 has been amended to include the subject matter of dependent claim 23, and corresponding amendments have been made to claims 3, 22 and 23 by the cancellation of these claims.

Reconsideration and allowance of the application are respectfully requested.

**Information Disclosure Statements**

Applicant expresses appreciation for inclusion with the Office Action of an initialed copy of the Information Disclosure Statement form filed with the Information Disclosure Statement on October 4, 2010 so that the Examiner's consideration of the Information Disclosure Statement is of record.

**Priority**

Applicant once again acknowledges the Examiner's indication regarding the parent PCT application, and reminds the Examiner that PCT/EP03/13873 entered the U.S. national stage and was awarded Application No. 10/582,223, and published as US 2007/0081950 A1. The Examiner is once again requested to review the file wrapper of this parent application at the Patent and Trademark Office, including the Office Actions mailed therein. If the Examiner needs any documents, the Examiner is requested to contact the undersigned.

**Restriction Requirement**

Applicant is permitting non-elected claims 16-21 to remain pending subject to rejoinder upon allowance of the elected subject matter.

**Response To Art Based Rejections**

The following art based rejections are set forth in the Office Action:

- (a) Claims 1, 3, 4, 6, 8, 11-13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668 and hereinafter "Tame-Said") in view of U.S. Patent No. 4,765,984 to Vellekoop et al. (hereinafter "Vellekoop").
- (b) Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman [apparently Vellekoop] and further in view of U.S. Patent No. 6,685,916 to Holme et al. (hereinafter "Holme").
- (c) Claims 11, 14 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said in view of Bauman [apparently Vellekoop] and further in view of U.S. Patent No. 6,682,722 to Majeti et al. (hereinafter "Majeti").
- (d) Claims 1, 3, 4, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-172315 to Lion Corp (hereinafter "Lion Corp") in view of U.S. Patent No. 3,511,914 to Wolkoff et al. (hereinafter "Wolkoff").
- (e) Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01-172315 to Lion Corp in view of Wolkoff et al., U.S. Patent No. 3,511,914, and further in view of Holme.

(f) Claims 6-9, 11, 14 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp in view of Wolkoff, and further in view of Majeti.

(g) Claims 5, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp in view of Wolkoff, and further in view of U.S. Patent No. 6,703,000 to Ning et al. (hereinafter "Ning").

Initially, Applicant notes that the rejections set forth in paragraph (b) and (c) above improperly refer to Bauman (US 3,928,618) because Bauman is not used in the rejection of the claims to which Bauman is stated to have been applied. While it is assumed that Vellekoop is the intended citation, Bauman is cited throughout each of the rejections and no mention is made of Vellekoop. Therefore, any of these rejections is maintained, the Examiner is requested to clarify the rejection, and not to make the next action final.

#### **Reponses to Rejections set forth in paragraphs (a), (b) and (c)**

In response to these grounds of rejection, Applicant submits that Tame-Said in view of Vellekoop does not teach or suggest the subject matter recited in Applicant's claims for at least the reasons set forth herein, and none of the documents used in the rejections of record, whether taken alone or in any combination, overcomes the deficiencies of any combination of Tame-Said and Vellekoop.

According to Applicant's invention, calcium pyrophosphate has been surprisingly found to exhibit improved stain removal when incorporated into a lozenge comprising a water-soluble lozenge base. Applicant has found that the tooth-whitening effectiveness of calcium pyrophosphate is not limited to mechanically applied (e.g., by brushing action) oral compositions

such as dental creams, but is seen to a surprisingly high degree in a lozenge composition that dissolves in the oral cavity owing to the water- soluble lozenge base.

Applicant's independent claim 1 is directed to a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials, said composition comprising:

- a) a water-soluble lozenge base,
- b) lozenge additives, and
- c) a tooth whitening agent comprising calcium pyrophosphate, said calcium pyrophosphate is present in an amount of between 1.5 % and 4.0 % by weight of the composition.

In contrast, Tame-Said discloses a toothpaste and mouthwash composition in tablet form which dissolves in the mouth. The object of the composition of Tame-Said is the prevention of periodontal disease or caries (abstract; page 1, lines 8-13).

Tame-Said teaches that each tablet comprises ascorbic acid, sodium bicarbonate, tricalcium phosphate, sodium lauryl sulfate, arabic gum, natural sweeteners and flavouring agents. Tame-Said is silent on the use of calcium pyrophosphate in the composition. Tame-Said teaches a considerably higher weight percentage of polishing agent, i.e., 11.59% of tricalcium phosphate (40mg. of tricalcium phosphate to 345 total mg.) then recited in Applicant's independent claim 1. Thus, Applicant's independent claim 1 is distinguished from Tame-Said by at least the amount of calcium pyrophosphate being between 1.5 % and 4.0 % by weight of the composition.

Vellekoop does not overcome the deficiencies of Tame-Said. One having ordinary skill in the art would not have combined the disclosure of Tame-Said and Vellekoop in view of their different disclosures as will be readily apparent from the discussion below. Moreover, any

combination of Tame-Said and Vellekoop would not arrive at Applicant's recited subject matter.

Vellekoop discloses a single unit dose oral product such as a chewable bead or lozenge (column 3, lines 36-39). Vellekoop teaches that the oral product must contain at least 40 % by weight of a liquid vehicle (see claim 1 and column 5, beginning at line 25). The lozenge of Applicant's claim 1 thus differs from the oral product of Vellekoop in that Applicant's lozenge comprises more than 75% by weight of solid materials.

Moreover, the oral product of Vellekoop preferably contains a dentally acceptable water-insoluble polishing agent in an amount of about 5-25 %, preferably 10-20% by weight (column 5, lines 55-58). The polishing agent may be selected from calcium carbonate, calcium pyrophosphate or others (column 5, lines 59-66). Consequently, the lozenge of Applicant's claim 1 further differs from the oral product of Vellekoop in that calcium pyrophosphate is present in an amount of between 1.5 and 4.0 % by weight of the composition.

Accordingly, even if one having ordinary skill in the art would have been prompted to replace calcium pyrophosphate of Vellekoop for tricalcium phosphate in the tablet of Tame-Said, Applicant's recited range of between 1.5 % and 4.0 % by weight of the composition would not be at hand. Each of Tame-Said and Vellekoop teaches a considerably higher weight percentage of abrasive material used in lozenges. This is even more so, since the prior art considered calcium pyrophosphate as an abrasive material with a particularly low polishing effect as compared to, for example, calcium carbonate (see Applicant's specification at page 2, lines 17-18). Thus, one having ordinary skill in the art seeking to provide a tooth whitening lozenge following the teachings of Tame-Said and/or Vellekoop would thus be directed to even higher amounts of calcium pyrophosphate than the lower limit of 5 % by weight in Vellekoop.

According to Applicant's disclosure, the use of abrasive materials such as calcium

pyrophosphate in confectionary such as lozenges would not be expected to cause a tooth whitening effect comparable to the effect when used in compositions intended for continuous chewing (Applicant's specification at page 3, line 31 to page 4, line 6). This is a rather intuitive prejudice of the prior art since lozenges are not chewed to the same extent as chewing gum. As a consequence the stain removal effect of the abrasive material would be expected to be insignificant due to the negligible mechanical rubbing on the tooth surface.

However, according to the present invention, it has surprisingly been found that calcium pyrophosphate in an unexpectedly low amount of between 1.5 % and 4.0 % by weight of a lozenge composition comprising more than 75% by weight of solid material has a particularly efficient stain removal effect. This is even more surprising since the effect is significantly increased as compared to calcium carbonate, which has been considered to be a more efficient abrasive material in the prior art. As an example, a lozenge composition comprising 2.08% by weight of calcium pyrophosphate is approximately 7 times more efficient than comparable prior art compositions (see Table 1 on page 14 of Applicant's specification). This surprising effect is certainly non-obvious and in no way foreshadowed by the cited prior art.

Holme and Majeti do not overcome the deficiencies of Tame-Said and Vellekoop for at least the reasons set forth above. Moreover, Holme and Majeti do not disclose the combination of features recited in the claims under rejection.

For example, Majeti is used in the rejection for its disclosure of urea peroxide as a bleaching agent. However, the dependent claims each recite the presence of urea which is disclosed in Appellant's specification, at page 7, lines 14 and 15, as a plaque acid buffer. In contrast, the rejection contends that Majeti discloses urea peroxide as a bleaching agent. There is no teaching or suggestion in the documents used in the rejection of the inclusion of urea in a

solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials as recited in Applicant's claims. In this regard, Applicant has previously submitted this argument; however the present rejection does not address Applicant's arguments.

Accordingly, the rejection is without sufficient basis in relying upon a bleaching agent of urea peroxide in the prior art, and does not establish the obviousness of Applicant's recited subject matter including urea let alone urea in the concentrations recited in Appellant's claims.

Still further, Applicant submits that any combination of the cited documents would not arrive at the subject matter recited in each of Applicant's dependent claims at least for the reasons set forth above, and for the additional features recited in each dependent claim in combination with the subject matter from their parent claims.

Thus, for at least the reasons set forth above, the rejections are without appropriate basis and should be withdrawn.

#### **Reponses to Rejections set forth in paragraphs (d), (e), (f) and (g)**

With regard to the rejections based upon Lion Corp, Applicant initially notes that Lion Corp was previously used in rejections in the Office Action dated December 7, 2009 and was argued in Applicant's response filed March 4, 2010. However, the present rejections have improperly not addressed Applicant's previous arguments pertaining to Lion Corp

Still further, the rejections do not state that an English translation of Lion Corp is being used. In this regard, Applicant notes that a machine English translation of JP 2580661B (which is the granted patent related to Lion Corp), downloaded from the JPO website, was previously submitted by Applicant with the response filed March 4, 2010.

Thus, as previously argued by Applicant Lion Corp does not teach or suggest the subject matter recited in Applicant's claims for at least the reasons set forth herein, and none of the documents used in the rejections of record, whether taken alone or in any combination, overcomes the deficiencies of Lion Corp

Lion Corp relies on the chemical action of a ketone compound and/or an epoxy compound for chemical tooth whitening. The composition may be used in different delivery forms such as a toothpaste, a mouth wash, a troche or a chewing gum. In addition, the composition may comprise a variety of optional constituents such as abrasives, including amongst others calcium pyrophosphate. The only example featuring calcium pyrophosphate relates to a chewing gum composition. Therefore, Lion Corp fails to disclose a lozenge composition comprising calcium pyrophosphate as a tooth whitening agent.

Still further, Lion Corp is silent with respect to a lozenge composition comprising calcium pyrophosphate wherein the lozenge base is water-soluble.

Applicant directs the Examiner's attention to the machine English translation of JP 2580661B. With respect to the prior art, Lion Corp discusses at length the disadvantages of tooth-whitening agents based on mechanical work of abrasives. These are considered in the context of applying mechanical action, disclosing that there is an increased danger of wearing out a tooth, as see, the Detailed Description, second paragraph. As a solution, Lion Corp proposes a "chemical operation" making use of a ketone compound and/or an epoxy compound. The composition may optionally contain other ingredients like an abrasive such as calcium pyrophosphate. However, the choice of the "proper ingredient" is subject to the delivery form (page 2, beginning at line 25).

In other words, the delivery form in Lion Corp, for example tooth paste, mouth wash,

troches, or chewing gum, determines the choice of additional ingredients. Abrasives, such as calcium pyrophosphate are, however, exclusively mentioned in terms of mechanical action, that is with respect to delivery forms such as chewing gum. Significantly, the only example mentioning calcium pyrophosphate (Example 7) relates to a chewing gum composition. By contrast, the example relating to a troche composition (Example 6) is silent on any form of abrasives, in particular on calcium pyrophosphate. This is perfectly in line with the general recommendations in Lion Corp on mechanical/masticator action and the corresponding choice of optional ingredients.

Therefore, Lion Corp does not provide any teaching or suggestion of a tooth whitening lozenge composition comprising a water-soluble lozenge base and calcium pyrophosphate. Lion Corp does not even remotely acknowledge a beneficial effect of abrasives in non-masticatory delivery forms, such as lozenges. The tooth whitening effect of a calcium pyrophosphate containing lozenge is therefore highly surprising and non-obvious in view of the cited prior art.

Expanding upon the above, Lion Corp therefore discloses a composition for oral cavity application, effective in chemically removing stains, plaques, food refuses, nicotine, etc., attached or deposited on the tooth, by compounding a ketone compound and an epoxy compound (Abstract). The oral composition is used in the form of a dentifrice (e.g. tooth paste), mouth wash, troche or chewing gum. Example 7 discloses a chewing gum composition comprising 2.0 % of calcium pyrophosphate. The subject-matter of Applicant's claim 1 thus differs from Lion Corp in that the tooth whitening composition is a lozenge composition comprising calcium pyrophosphate in an amount of between 1.5 % and 4.0 % by weight.

It is respectfully submitted that Lion Corp does not disclose a lozenge composition with 2.0 % by weight of calcium pyrophosphate. Neither is such a composition obvious in view of

Lion Corp since a prejudice existed in the prior art that considerably higher amounts of abrasive material are needed, if at all effective, in confectionary compositions such as lozenges as compared to chewing gum. This prejudice is also quite plausible since chewing gums are intended for continuous chewing which exposes the composition to much higher degree of mechanical rubbing action. Thus, any amount of abrasive material present in chewing gum is expected to have a significantly larger effect than the same amount of abrasive material present in a lozenge composition. This is also the rationale behind the considerably higher amounts of abrasive material in the lozenge compositions described in the prior art.

This deficiency of Lion Corp is not cured by Wolkoff or any other cited document. The surprising finding that a lozenge composition comprising calcium pyrophosphate in an amount as low as 1.5-4.0 % by weight is in no way suggested or foreshadowed by any teaching in the prior art.

It is respectfully submitted that Wolkoff is not relevant in this context since it does not relate to tooth whitening lozenge compositions, let alone compositions comprising abrasive materials. Thus, Wolkoff does not provide any guidance for one having ordinary skill in the art towards an effective amount of abrasive material in a lozenge composition. The fact that lozenge bases were known in the prior art, and that calcium pyrophosphate is known as an abrasive material is not disputed by the Applicant. However, the surprising tooth whitening efficiency of amounts as low as 1.5 - 4.0 % by weight of calcium pyrophosphate in a lozenge composition comprising more than 75% by weight of solid material is not taught or suggested by Lion Corp taken alone or with Wolkoff.

Holme, Majeti and Ning do not overcome the deficiencies of Tame-Said and Vellekoop for at least the reasons set forth above. Moreover, Holme, Majeti and Ning do not disclose the combination of features recited in the claims under rejection.

For example, Majeti is used in the rejection for its disclosure of urea peroxide as a bleaching agent. However, the dependent claims each recite the presence of urea which is disclosed in Appellant's specification, at page 7, lines 14 and 15, as a plaque acid buffer. In contrast, the rejection contends that Majeti discloses urea peroxide as a bleaching agent. There is no teaching or suggestion in the documents used in the rejection of the inclusion of urea in a solid oral tooth whitening lozenge composition comprising more than 75% by weight of solid materials as recited in Applicant's claims. In this regard, Applicant has previously submitted this argument; however the present rejection does not address Applicant's arguments.

Accordingly, the rejection is without sufficient basis in relying upon a bleaching agent of urea peroxide in the prior art, and does not establish the obviousness of Applicant's recited subject matter including urea let alone urea in the concentrations recited in Appellant's claims.

Still further, Applicant submits that any combination of the cited documents would not arrive at the subject matter recited in each of Applicant's dependent claims at least for the reasons set forth above, and for the additional features recited in each dependent claim in combination with the subject matter from their parent claims.

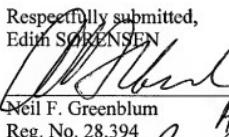
For at least the reasons set forth above, the rejections are without appropriate basis and should be withdrawn.

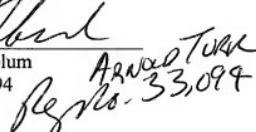
**CONCLUSION**

Entry and consideration of the present amendment, reconsideration of the Office Action, and allowance of the present application and all of the claims therein are respectfully requested and believed to be appropriate.

Should the Examiner have any questions or comments regarding this response, or the present application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,  
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